

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (canceled)
2. (previously presented) The method according to Claim 66 wherein the urine sample comprises a plurality of urine samples from the mammal that are obtained intermittently or continuously.
3. (canceled)
4. (previously presented) The method according to Claim 66 wherein the step of detecting the antibody-NGAL complex comprises contacting the complex with a second antibody for detecting the NGAL.
5. (previously presented) The method according to Claim 66 wherein the mammal is a human.
6. - 8. (canceled)
9. (previously presented) The method according to Claim 66 wherein the antibody is a capture antibody for the NGAL and the antibody-NGAL complex is a capture antibody-NGAL complex.
10. (previously presented) The method according to Claim 9 wherein the step of detecting the antibody-NGAL complex comprises the steps of:

(1) separating any unbound material of the urine sample from the capture antibody-NGAL complex;

(2) contacting the capture antibody-NGAL complex with a second antibody for detecting the NGAL, to allow formation of a second complex between the second antibody and the capture antibody-NGAL complex;

(3) separating any unbound second antibody from the second antibody complex; and

(4) detecting the second antibody of the second antibody complex.

11. (previously presented) The method according to Claim 10 wherein the step (i) comprises the step of contacting the urine sample with a media having affixed thereto the capture antibody.

12. - 32. (canceled)

33. (previously presented) The method according to claim 66, wherein the obtained urine sample is the first urine output of the mammal immediately after the onset of the RTCI.

34. (canceled)

35. (previously presented) The method according to claim 66 wherein the urine sample is obtained within a period of time of the RTCI, the period of time selected from the group consisting of 2 hours, 1 hour, and 30 minutes.

36. (canceled)

37. (previously presented) The method according to claim 66 wherein the RTCI is effected by an event upon the mammal, the event selected from the group consisting of: (a) a surgical procedure selected from the group consisting of open heart surgery, cardiac surgery, and vascular surgery; and (b) kidney transplantation.

38. - 54. (canceled)

55. (currently amended) The method according to claim 66 wherein the level of detected antibody-NGAL complex correlates with the extent of the ~~[[acute]]~~ ischemic renal tubular cell injury.

56. - 59. (canceled)

60. (currently amended) The method according to claim 66 wherein the mammal is a patient who has undergone open heart surgery, and wherein an at least 10-fold increase in the level of antibody-NGAL complex in a urine sample obtained at 2 hours after surgery, correlates with the RTCI progressing to acute renal failure (ARF).

61. - 65. (canceled)

66. (previously presented) A method for the detection of a renal tubular cell injury (RTCI) in a mammal, the RTCI being an ischemic renal injury, comprising the steps of:

(a) contacting a urine sample obtained within four hours of the RTCI from a mammal suspected of having the RTCI, with an antibody for a biomarker consisting of NGAL, to allow formation of a complex of the antibody and NGAL;

(b) detecting the antibody-NGAL complex; and

(c) correlating the level of detected antibody-NGAL complex to the mammal having the RTCI.

67. (new) A method for the detection of a renal tubular cell injury (RTCI) in a mammal, the RTCI being an ischemic renal injury, comprising the steps of:

(a) contacting a urine sample obtained within twenty-four hours of the RTCI from a mammal suspected of having the RTCI, with an antibody for a biomarker consisting of NGAL, to allow formation of a complex of the antibody and NGAL;

(b) detecting the antibody-NGAL complex; and

(c) correlating the level of detected antibody-NGAL complex to the mammal having the RTCI.

68. (new) A method for the detection of a renal tubular cell injury which is an ischemic renal injury in a human patient, comprising the steps of :

1) contacting a urine sample obtained from a human patient with an antibody for a biomarker consisting of NGAL, appearing within the first 24 hours of the onset of the ischemic renal injury, to allow formation of a complex of the antibody and NGAL; and

2) detecting the antibody-NGAL complex.

69. (new) The method according to Claim 68 wherein a plurality of urine samples from the patient is obtained intermittently.

70. (new) The method according to Claim 69 wherein the urine samples are obtained continuously.

71. (new) The method according to Claim 68 wherein the step of detecting the antibody-NGAL complex comprises contacting the complex with a second antibody for detecting NGAL.

72. (new) The method according to claim 68 for further monitoring the effectiveness of a treatment for the renal tubular cell injury, comprising the further steps of :

3) contacting at least one post-treatment urine sample from the human patient experiencing the renal tubular cell injury, and receiving a treatment therefore, with a capture antibody for NGAL to allow formation of a complex of the antibody and NGAL; and

4) detecting for the presence of NGAL in the post-treatment urine sample by detecting the antibody-NGAL complex.

73. (new) The method according to Claim 72 wherein the step 4) of detecting the antibody-NGAL complex comprises the steps of : (4i) separating any unbound material of the urine sample from the capture antibody-NGAL complex; (4ii) contacting the capture antibody-NGAL complex with a second antibody for detecting NGAL, to allow formation of a complex between

NGAL and the second antibody; (4iii) separating any unbound second antibody from the NGAL-second antibody complex; and (4iv) detecting the second antibody of the NGAL-second antibody complex.

74. (new) The method according to Claim 72 wherein the step 3) comprises the step of contacting the urine sample with a media having affixed thereto the contact antibody.

75. (new) A method according to claim 68, wherein the urine sample comprises up to 1 milliliter of the first urine from the patient.

76. (new) The method according to Claim 68 for the detection of ischemic renal injury wherein the urinary NGAL, measured within two hours of kidney transplantation, is predictive of acute renal failure.

77. (new) The method according to Claim 68 for the detection of post-operative acute renal failure in human patients after open heart surgery, wherein the urinary NGAL measured within two hours after surgery is predictive of acute renal failure.

78. (new) The method of Claim 77 wherein patients who subsequently develop acute renal failure display a greater than 10-fold increase in NGAL within 2 hours after surgery, expressed as ng NGAL/mg creatinine, as compared to those who do not.

79. (new) The method of Claim 77 wherein patients who subsequently develop acute renal failure display a greater than 20-fold increase in NGAL within 4 hours after surgery, expressed as ng NGAL/mg creatinine, as compared to those who do not.

80. (new) The method of Claim 68 wherein the urine sample is a sample of urine within four hours following the renal tubular cell injury.

81. (new) The method of Claim 68 wherein the urine sample is a sample of urine within two hours

following the renal tubular cell injury.

82. (new) A method of identifying the extent of a renal tubular cell injury, which is an ischemic renal injury, caused by an event, comprising the steps of:

1) detecting in at least one urine sample obtained from a human patient the presence of a biomarker consisting of NGAL, appearing within the first 24 hours of the onset of the ischemic renal injury; and

2) determining the extent of the renal tubular cell injury based on the time for onset of the presence of NGAL in the urine sample, relative to the time of the event.

83. (new) The method according to Claim 82 wherein the event is a surgical procedure.

84. (new) The method according to Claim 82 wherein the event bringing about the ischemic renal injury is diminished blood supply to the kidneys, impaired heart function, surgical procedures or patients in intensive care units.